GMTA/DITTA Workshop on Reliance

- **Scene Setting**: What is reliance and why is it important?
- **Session 1**: Reliance in a premarket setting
- **Session 2**: Reliance in a post market setting
- **Next Steps**
Objective 5: To be recognized as an International Reference Regulatory Authority.

Consolidation of Anvisa leading role in the international scenario, ensuring high standards in all regulatory operations.
Reliance Activities in Inspections

• **Pathways for the grant of GMP Certificates issued by Anvisa**

1. GMP Inspection conducted by Anvisa inspectors with the issuance of an Inspection Report attesting if the company has a Quality Management System and complies with the Good Manufacturing Practices.

2. Based on the information from other Inspection Reports issued by recognized authorities accompanied by a Risk Analysis.

3. Based on MDSAP Inspection Reports and Certificates.

Reference Legislation: RDC 687/2022
Reliance Activities in Inspections and Resources

**CPROD – Coordination for Inspections and Law Enforcement for Medical Devices**

- Inspections/audits of companies
- GMP Certification using risk analysis + reliance mechanisms and Anvisa Inspection Reports.
- Investigation of complaints/quality defects and law enforcement actions

24
## GMP Certification in Numbers

<table>
<thead>
<tr>
<th>YEAR</th>
<th>GMP Certificates Issued Based on MDSAP Reports by CAUPS (total and % of total)</th>
<th>GMP Certificates Issued Based on Anvisa Inspection + risk matrix by CPROD</th>
<th>Total International GMP Certificates issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>38 (4.7%)</td>
<td>770 (95.3%)</td>
<td>808</td>
</tr>
<tr>
<td>2018</td>
<td>107 (19.3%)</td>
<td>447 (80.7%)</td>
<td>554</td>
</tr>
<tr>
<td>2019</td>
<td>374 (48.7%)</td>
<td>394 (52.3%)</td>
<td>768</td>
</tr>
<tr>
<td>2020</td>
<td>544 (49.1%)</td>
<td>564 (50.9%)</td>
<td>1108</td>
</tr>
<tr>
<td>2021</td>
<td>529 (51.4%)</td>
<td>500 (48.6%)</td>
<td>1029</td>
</tr>
<tr>
<td>2022</td>
<td>621 (59.7%)</td>
<td>419 (40.3%)</td>
<td>1040</td>
</tr>
<tr>
<td>2023</td>
<td>659 (59.1%)</td>
<td>456 (40.9%)</td>
<td>1115</td>
</tr>
</tbody>
</table>
Other Post Market Activities

- **Resources allocated to other activities**
  - Increased number of Post Market Compliance (PMC) Inspections.
    - 85 inspections in the last 4 years (*pandemic)
    - Previously approx. 4 inspections per year.
  - Increased activities upon the receipt of MDSAP 5-day notice
    - 20 MDSAP 5-day notices – all were assessed, and investigations were conducted:
      - 9 immediate enforcement actions, for example: prohibition of importation;
      - 11 technical complaints confirmed;
      - 01 penalty applied.
Other Activities

• **Resources allocated to other activities**
  • Investigation of Complaints related to Quality Defects;
    • More than 1600 investigations in the last 4 years* (*pandemic)
  • Launch of Monitoring Programs focused on specific products – laboratory testing.
    • COVID19 diagnosis tests
    • Needles and Syringes
    • Infusion sets
Monitoring Programs

- **COVID19 diagnosis tests** *(closed January 2023)*
  - 536 laboratory tests conducted
  - 64.9% approved
  - 35.1% not approved

- **Needles and Syringes** *(started August 2023)*
  - 21 lab tests conducted
  - 100% approved

- **Infusion sets** *(started September 2023)*
  - 15 lab tests conducted
  - 66.7% approved
  - 33.3% not approved

Data obtained on 29 February 2023
Monitoramento pós-mercado da qualidade de dispositivos para diagnóstico *in vitro* da COVID-19: análises laboratoriais

### Resultados obtidos

- Não conforme: 188 (35.93%)
- Conforme: 348 (64.07%)

### Amostras analisadas

<table>
<thead>
<tr>
<th>Teste</th>
<th>Quantidade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teste rápido</td>
<td>415</td>
</tr>
<tr>
<td>Ensaio de quimioluminescência</td>
<td>56</td>
</tr>
<tr>
<td>Ensaio de ácidos nucleicos</td>
<td>41</td>
</tr>
<tr>
<td>Ensaio imunoenzimático</td>
<td>22</td>
</tr>
<tr>
<td>Soro controle</td>
<td>2</td>
</tr>
</tbody>
</table>

Outras ações

Data da última atualização: 29/02/2024
Anvisa Silver Jubilee Celebration

The Agency celebrates 25 years of contributions to public health and to the quality of life of Brazilian citizens.